Break-out group I:
Morphological, Geometrical, and General Terminology

ANSI-Nanotechnology Standards Panel

Presented by

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FDA

Top 5 Critical Issues Related to Nomenclature

1. **Characterization metrology/ Measurement test methods**

2. **Risk management/ Assessment/Communication**

3. **Description of characterization properties**

4. **Toxicity Effects/Environmental Impact**

5. **Applications**

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Characterization metrology/ Measurement test methods

- **Physical: size, shape, surface characteristics, morphology**
- **How do you convey a description of a structure: analytically (space group, atomic positional parameters), by name?**
- **Solid, liquid, gas, free-flowing or confined**
- **Naturally occurring versus engineered**
- **Chemical Characteristics – Stability in ambient; Physical characteristics – optical electronics magnetic, etc; Biological characteristics – reactivity towards biochemicals; Structural characteristics – morphological polymorphism**

Risk management/Assessment/Communication

- **Risk characterization**

- **Containment Procedures**

- **Environmental**

- **Exposure**

- **Workforce**

- **Use balanced risk/benefit approach; benefit vs. risk**

- **Relationship to environmental impact assessment**

- **Hazard identification**

- **Exposure assessment; Dose-response assessment**

- **Communication to regulators; Public sector communication**

- **Persistence (life time); End of life issues**

Description of characterization properties

- **Naturally occurring versus engineered.**
- **For complex species, need to distinguish different "polymorphs", e.g., CNTs.**
- **Physical: size, shape, surface characteristics, morphology**
- **Porosity: open, closed, size**
- **Magnetic; Optical; Thermal; Electrical and electronic**
- **Bioactivity**
- **Biokenetics**
- **Surface area; Surface structures/functionalities**
- **Solid, liquid, gas**
- **Discrete nanoforms (particles, tubes, rods) versus nanostructured bulk materials (nanostructured or patterned surfaces, nanoporous materials, nano organized macrosystems)**
- **Crystalline – amorphous**
- **Inorganic, organic, hybrid**
- **Characteristics – define shape by words, analytically**
- **Characteristics chemical: activity, composition, reactivity**
- **Characteristics: Differentiating name chemicals with different sizes; same chemical – different forms nanotubes of different durability**

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Toxicity Effects/Environmental Impact

- **Energy; Energy Conservation**
- **Land; Long term soil health**
- **Air; Air Quality (Clean Air Act); Water; Water quality; Waste streams (Clean water act)**
- **Pollution prevention; Waste minimization; Green Chemistry**
- **Disposal/Life cycle issues (production, use, release, medium, persistence)**
- **Total impact: manufacture; use; end of life**
- **Solid/hazardous waste (CERCLA/RCKA)**
- **Disposal, Fate, Exposure; Model/Route of exposure; Measures of exposure**
- **Relationship to risk management process**
- **Distributive considerations: discussion of risk across populations**
- **Use balanced risk/benefit approach**

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Applications

- **Efficacy or performance, i.e., Does it work? How can you tell/assess?**
- **Agriculture and food**
- **Hierarchical assembly**
- **Degradation of host or matrix resulting in the release of nanoparticles (in a nanocomposite material)**
- **Free versus bound nano particles**
- **Interaction/interactive with other products: free-standing, devices**
- **Medical therapeutic**
- **Water purification**
- **Education and Training: K-12 through grey**
- **Drug delivery**
- **Sensors**
- **Scaling Effects**
- **Applications: Medical, Therapeutic, drug delivery (cancer, etc.), diagnostic**

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Discussion of implementation questions

- Standards work underway

- Stakeholders missing from this group

- Cross-cutting issues

- Impediments to the generation and acceptance of a universal nomenclature

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Broader Issues: Top Three

- **Standard test methods**

- **Toxicity**
  - ➢ **Tox Testing Methods**
  - ➢ **Better Evaluation tools for cellular damage, toxicity as a function of exposure**

- **Public perception/issues**

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General Comments